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STATE OF DELAWARE **DEPARTMENT OF STATE**

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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE: CONTROLLED SUBSTANCE COMMITTEE

DATE AND TIME: Wednesday, May 29, 2012 at 9:00 a.m.

PLACE: Buena Vista Conference Center, Buck Library, First Floor,

661 S. DuPont Highway, New Castle, Delaware 19720

APPROVED: June 26, 2013

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Philip Kim, M.D., Medical Representative
Ann Dominick, APN, Nursing Representative
Stephen Ruggles, PA-C, PA Representative
Howard Simon, R.Ph, Pharmacy Representative, Chair
Bonnie Wallner, R.Ph., Pharmacy Representative
Mark Hanna, Public Representative
David W. Dryden, R.Ph., J.D., Director Office of Controlled Substances

MEMBERS ABSENT

Robert Flanagan, DVM, Vet Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

Catherine Simon, Administrative Specialist III Samantha Nettesheim, Pharmacist Administrator Eileen Kelly, Deputy Attorney General Lorena Hartnett, Court Reporter

ALSO PRESENT

Ray Hancock
Donna Farra
Don Holst
Lucy Somer
Sandra Robinson
Jeanne Chiquoine
Dr. Keith Sokoloff
Cheryl Heiks

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:01am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Simon, seconded by Ms. Wallner, to approve the minutes from the March 27, 2013 meeting as presented. The motion was unanimously carried.

PRESIDENT'S REPORT

Dr. Kremer thanked Ms. Simon for her work with the Advisory Committee and wishes her well as she takes a promotion to another agency.

UNFINISHED BUSINESS

Re-Review of Application for Penn Veterinary Supply, Inc.

The Committee re-reviewed the application for controlled substances registration of Penn Veterinary Supply, Inc., a wholesale drug distributor, due to previous criminal history of one of the owners of the company. DAG Kelly reported at the March 27, 2013 meeting that he was convicted of a violation against the controlled substances act in Pennsylvania. Supplemental documentation was submitted regarding the criminal charge. DAG Kelly explained that he did not submit a disposition from the court showing that he met the terms of his probation. A motion was made by Dr. Kremer, seconded by Mr. Simon, to approve the application of Penn Veterinary Supply, Inc. for a controlled substances registration contingent upon receipt of court disposition documents for the file. The motion was unanimously carried.

Continued Discussion of Requiring Continuing Education

DAG Davis-Oliva drafted language to add the requirement of continuing education for all registrants. Mr. Dryden summarized the requirements and reported that the draft language will be posted to the Register of Regulations June 1, 2013 and the hearing will take place at the August 28, 2013 meeting.

E-Prescribing Statutory Amendment Update

At the last meeting the Committee voted to accept the language as presented. DAG Kelly will put this in Bill form to submit for legislation.

NEW BUSINESS

Rules and Regulations Hearing – 9:30am

The hearing went on the record at 9:30am. The Committee members introduced themselves for the record. DAG Kelly stated the purpose of the public hearing is to consider adoption of proposed amendments to the Rules and Regulations which have been expanded for greater clarity and incorporate pertinent provisions from Chapter 47 of Title 16. Notice of the hearing was published in both The News Journal and Delaware State News on May 1, 2013. DAG Kelly entered into record Board Exhibits 1 and 2 - affidavits of publication. No written public comments were received by the Board office. Mr. Dryden stated that he believes that the proposed changes will be beneficial to the regulation of controlled substances. The written comment period will remain open for another 15 days. The Committee will deliberate and vote on the changes after all written comments have been reviewed at their next meeting on Wednesday, June 26, 2013 at 8am at Governor Bacon Health Center. The hearing went off the record at 9:36am.

Proposal to Deny Hearing – Dr. Keith Sokoloff

The hearing went on the record at 9:48am. The Committee members introduced themselves for the record. DAG Kelly stated the purpose of the hearing is to consider the application for controlled substances registration of Dr. Keith Sokoloff. At its meeting on March 27, 2013, the Committee reviewed the application for controlled substances registration of Dr. Sokoloff and voted to propose to deny his application. DAG Kelly marked into the record Committee Exhibit 1, Dr. Sokoloff's application for controlled substances registration and supporting

documentation, including a previous Public Order and communication from the Committee regarding the hearing. DAG Kelly also entered into the record Applicant Exhibits 1 and 2, letters of recommendation from David S. Jezyk, M.D. and Vincent E. Schaller, M.D. Dr. Sokoloff was sworn in and provided testimony. Committee members directed questions to Dr. Sokoloff. Mr. Dryden was sworn in and provided testimony. Committee members and Dr. Sokoloff directed questions to Mr. Dryden. The hearing went off the record for deliberations at 10:13am. The hearing went back on the record at 10:24am. Committee members asked further questions of Dr. Sokoloff. The hearing went off the record for deliberations at 10:25am. The hearing went back on the record at 10:41am. A motion was made by Dr. Kremer, seconded by Mr. Simon, to recommend approval Dr. Sokoloff's application for controlled substances registration, contingent upon approval of his pardon by the Governor, with the following limitations: he can prescribe only Schedules III-V drugs, he cannot store or dispense controlled substances, he must notify the Committee if he changes or adds practice locations, and if he wishes to amend these terms he must come before the Committee for approval. The motion was carried unanimously. The hearing went off the record at 10:42am.

Discussion of Telemedicine Practitioners Issue

Mr. Dryden reported that recently several physicians have applied for controlled substances registrations practicing via telemedicine. The Medical Practice Act allows for physicians to practice via telemedicine avenues, i.e. Skype. The issue is that Delaware requires a physical Delaware location in order to prescribe controlled substances in Delaware.

Review of Board of Pharmacy Draft Syringe Law

The Committee reviewed the proposed draft language changes to the Board of Pharmacy statute regarding the sale of hypodermic syringes. The draft has passed in the Senate with one amendment. Mr. Dryden explained that the law allows pharmacists to dispense syringes without a prescription to patients over the age of 18 with positive ID.

DIRECTOR'S REPORT

Case/Diversion Review

Mr. Dryden reported that he and Ms. Kluger have been conducting investigations as required.

Prescription Monitoring Program (PMP) Review

Ms. Nettesheim has been busy working on grant proposals and processing reports. She reported that there are currently about 1700 registrants in the PMP, about 600 of which are pharmacists. Last month the amount of report requests tripled. There are 15 states currently sharing data with InterConnect and Delaware will be connected soon.

National Disposal

The drug take-back event held on April 27, 2013 was very successful. More drugs were collected during this event than ever before.

Current Event Review

No report.

COMMITTEE REPORTS

Medical Examiner's Report

No report.

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DEA Report

No report.

Substance Abuse Report

No report.

Law Enforcement Report

Agent Ray Hancock reported the PMP is working well. He noted that they are seeing an influx of more out-of-state forged prescriptions. Oxycodone 30mg continues to be the #1 abused drug in DE.

Regulatory Committee Report

No report.

Legislative Committee Report

No report.

INSPECTION REPORT

No report.

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENTS

Don Holst thanked the Committee for their work on the drive-through regulations.

EXECUTIVE SESSION

No executive session was needed.

NEXT SCHEDULED MEETING

The next regular meeting will be held on Wednesday, April 28, 2013 at 9:00am.

ADJOURNMENT

A motion was made by Dr. Garcia, seconded by Dr. Kremer, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 10:46am.

Respectfully submitted,

David W. Dryden, R.Ph., J.D.